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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/733,172

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Robert A. Janssen

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EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,172	JANSSEN ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,9,10,14,15 and 42-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,9,10,14,15 and 42-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-3, 7-15 and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modha et al. (US Patent Application Publication No. 2003/0118837) in view of Elton (US Patent 5,160,790).

4. Regarding claims 1 and 7, Modha discloses an elastomeric glove comprising:

a substrate body including a layer made of an elastomeric material, said substrate body defining an inner surface and an outer surface (¶ [0022]-[0024], Figs. 1-2, glove 20 having inner surface and outer surface); and

a coating overlying the inner surface of said substrate body and defining a user-contacting surface of the glove (¶ [0024], Fig. 2, coating 26),

an active agent comprising a skin-conditioner, wherein the skin-conditioner comprises a humectant (¶ [0054], polypropylene glycol and polyethylene glycols. Examiner interprets the limitation of a humectant broadly to include moisture-retaining materials. See online encyclopedia article on humectants.).

Modha discloses the invention as substantially claimed, see above. However, Modha lacks a crosslinked hydrogel network as claimed [claim 1]. Elton discloses a lubricious organic coating (col. 2, lines 18-30), adaptable for coating rubber articles (col. 5, lines 57-61). Elton further discloses:

a coating comprising a crosslinked hydrogel network (col. 5, lines 44-56, crosslinked system);

within which is retained an active agent capable of imparting a benefit to a user (col. 4, lines 34-37, antioxidants),

wherein said hydrogel network is formed from one or more polymers (col. 4, lines 29-53, especially lines 31-33, Poly vinyl pyrrolidone (PVP)),

at least one of said polymers being formed from at least one monomer that is hydrophilic and water-soluble (see online encyclopedia article on Poly vinyl pyrrolidone. Examiner notes that PVP is formed from vinyl pyrrolidone, a ketone. Therefore it is hydrophilic and water-soluble.),

wherein said monomer is a derivative of a vinyl pyridine (PVP forming Poly vinyl pyrrolidone),

wherein said active agent is releasable from said network when said coating is contacted with an aqueous environment (col. 7, lines 25-35, antioxidants used in

amounts of 0.01 – 1%. It is the Examiner's position that the disclosed antioxidants are not bonded to the hydrogel matrix and are substantially releasable.),

wherein the crosslinked hydrogel network is substantially water-insoluble (cols. 3-4, lines 56-60, 65-7), and

achieves a water content of from about 20% to about 90% when exposed to water (hydrogel fully capable of achieving water content of 20-90%).

Elton provides the advantage of reducing friction between a medical device and skin to reduce skin abrasion (col. 1, lines 5-17, especially lines 13-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Modha as discussed with the crosslinked hydrogel network as taught by Elton in order to reduce skin abrasion.

Examiner notes that both Modha and Elton disclose substances interpreted as an active agent. Modha discloses a skin-conditioner (§ [0054], polypropylene glycol), and Elton discloses an antioxidant (col. 4, lines 34-37, antioxidants).

Modha discloses the invention as substantially claimed, see above. However, Modha is silent regarding the capability of achieving a water content of from about 20-90% as claimed [claim 1]. Examiner interprets the limitation of a of water content capability as a result-effective variable, subject to experimentation and testing. There is an optimum water content capability such that moisture content of a coating layer will be balanced with the moisture content of a user's skin surface. Determining this value is subject to experimentation and testing to produce a glove with the best donning and wearing characteristics. Therefore, it would have been obvious to one of ordinary skill in

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the art at the time the invention was made to adjust the water content capability to about 20-90% in order to provide the best donning and wearing characteristics. See MPEP 2144.05(II)(A,B). See in re Boesch and Slaney, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

5. Regarding claims 2 and 3, Modha discloses an elastomeric material of a substrate body comprising natural rubber latex (§ [0023], substrate body 24 formed from natural rubber latex).

6. Regarding claims 9 and 10, Modha discloses the invention as substantially claimed, see above. However, Modha is silent regarding the capability of achieving a water content of from about 35-85% or 50-80% as claimed [claims 9 and 10]. Examiner interprets the limitation of a of water content capability as a result-effective variable, subject to experimentation and testing. Regarding rationale and motivation, see discussion of claim 1 above.

7. Regarding claim 14, Modha discloses a coating thickness from about 0.1-20 μm (§ [0036], range of 0.5-20 μm overlapping claimed range).

8. Regarding claim 15, Modha discloses the invention as substantially claimed, see above. However, Modha is silent regarding coating weight as claimed [claim 15].

However this parameter is deemed a matter of design choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Relative weight of a coating to a substrate is dependent on the coating thickness. For example, a thicker coating will naturally have a higher ratio of coating to glove material. A heavier coating layer will have more lubricity and easier

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donning ability than a lighter coating layer. Thus, it would have been obvious to one of ordinary skill in the art to modify the coating weight ratio as claimed as a mere design choice lacking any criticality of comprising from about 0.001-0.5 grams / gram of a glove, as being merely preferable for the intended purpose of achieving optimum lubricity and donnability. Where the only difference between the prior art and the claims was a recitation of relative coating weight ratio of the claimed device and a device having the claimed relative coating weight ratio would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art.

“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

9. Regarding claims 45 and 46, Modha discloses a humectant (¶ [0054], polypropylene glycol and polyethylene glycols).

10. Regarding claims 47 and 48, Modha discloses the invention as substantially claimed, see above. However, Modha lacks an antioxidant as claimed [claims 47 and 48]. Elton discloses an antioxidant (col. 7, lines 25-35, 2,2'- methylenebis (4-methyl-6-t-butyl phenol), a phenol derivative). Elton provides the advantage of improving oxidative stability. In other words, natural rubber articles are subject to oxidative degradation, which can be slowed by the antioxidant as taught by Elton. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Modha as discussed with the antioxidant as taught by Elton in order to slow oxidative degradation.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Modha et al. (US Patent Application Publication No. 2003/0118837) in view of Elton (US Patent 5,160,790), further in view of Podell et al. (US Patent 4,548,844).

12. Regarding claim 6, Modha in view of Elton discloses the invention as substantially claimed, see above. However, Modha in view of Elton lacks a monomer including hydroxyethyl methacrylate (HEMA), as claimed [claim 6]. Podell discloses a latex rubber surgeon's glove coated with a hydrogel matrix (col. 4, lines 34-43). Podell further discloses HEMA monomers (col. 8, lines 55-63, especially lines 56-57). Podell provides the advantage of high degree of slip against damp or wet skin of a user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Modha in view of Elton as discussed with the HEMA as taught by Podell in order to provide a high degree of slip when donning a rubber glove.

13. Claims 42-44, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modha et al. (US Patent Application Publication No. 2003/0118837) in view of Elton (US Patent 5,160,790), further in view of Zimmerman (US Patent Application Publication No. 2003/0056276).

14. Regarding claims 42-44, 49 and 50, Modha in view of Elton discloses the invention as substantially claimed, see above. However, Modha in view of Elton lacks a skin conditioner comprising an emollient, lipid or botanical agent as claimed [claims 42-

44, 49 and 50]. Zimmerman discloses a cosmetic applicator in the form of a coated glove (§ [0003], [0004], [0018]). Zimmerman further discloses:

an emollient including jojoba and avocado oils, lipids (§ [0021], juices or oils, including jojoba and avocado); and

a botanical agent (§ [0021], juices or oils, including lavender, borage and almond).

Zimmerman provides the advantage of maintaining a therapeutic agent in contact with skin for an extended time period (§ [0031]). Regarding jojoba and avocado oils or botanical agents, Zimmerman provides the advantage of a natural agents that are substantially non-toxic and have few side effects. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Modha in view of Elton as discussed with the lipid and/or botanical agent as taught by Zimmerman in order to avoid toxicity and side effects of a therapeutic agent.

Response to Arguments

15. Applicant's arguments filed 18 September 2008 have been fully considered but they are not persuasive.

16. Applicant asserts that Modha, et al. is available only under 35 U.S.C. § 102(a) and (e). Examiner notes that Modha is not disqualified under 35 U.S.C. § 103(c), since "In order to be disqualified as prior art under 35 U.S.C. 103(c), the subject matter which would otherwise be prior art to the claimed invention and the claimed invention must be

commonly owned, or subject to an obligation of assignment to a same person, at the time the claimed invention was made or be subject to a joint research agreement at the time the invention was made.” See MPEP 706.02(I)(2), Establishing Common Ownership or Joint Research Agreement. Examiner notes that the assignments are recorded as executed on 06 and 12 April 2004, after the filing date of 19 August 2002 and publication date of 26 June 2003.

17. Applicant notes that Modha lacks a crosslinked hydrogel network. Examiner notes that Elton teaches a crosslinked hydrogel network.

18. Applicant asserts that modifying Modha in view of the PVP containing layer of Elton would not form a "user-contacting surface" of the glove, since Modha discloses a lubricant overlying the donning layer during use (Pg. 2, paragraph 24). Examiner notes that the presence of a lubricant does not preclude a crosslinked hydrogel network as taught by Elton from defining a user-contacting surface. In other words, the PVP containing layer of Elton will face the user instead of the outside surface. Additionally, a lubricant does not block or prevent the benefits of a crosslinked hydrogel network.

19. Examiner also notes that Modha discloses embodiments wherein the cited lubricant 32 covers portions not already covered by hydrogel coating 26 (¶ [0041], "... lubricant coating 32 may cover only those portions of the substrate body 30 not already covered by the hydrogel coating 26."). Therefore, in this embodiment lubricant 32 will not be placed between coating 26 and a wearer's skin. Additionally, Modha discloses lubricant 32 as optional (¶ [0054], ..."optional lubricant coating 32...").

20. Applicant reasons that the polyurethane and polyvinylpyrrolidone (PVP) layer of Elton is not configured to release an active agent upon contact with water, since the "antioxidant" disclosed by Elton is included to preventing oxidation of the monomers and the resulting polymers during formation of the polymeric layer (i.e., during polymerization of the polyurethane and PVP). Thus, this additive is included solely for the purpose of preventing oxidation of the polymer- not for any benefit of the wearer. In response to applicant's argument that the antioxidant of Elton is included for the purpose of preventing polymer oxidation and not to benefit a wearer, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). To clarify, the antioxidant of Elton is interpreted as imparting benefit both to a polymer and user.

21. If any amendments to the claims are desired for overcoming rejections of record, Examiner recommends phrasing them in positive language. While negative limitations are legitimate and do not preclude patentability, positive recitations are generally more effective. There is nothing inherently ambiguous or uncertain about a negative limitation, as long as it is properly supported by the specification. See MPEP 2173.05(i), Negative Limitations. However, adding language to positively claim structures and functions is generally more helpful in clearly defining the invention as compared to negative limitations, since the presence of a structure or function is more easily seen, depicted or discerned than its absence or omission.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ❖ Janssen, Robert A. US 20040107477
- ❖ Fuchs; Ingbert E. US 5483697
- ❖ Elton; Richard et al. US 5776611
- ❖ Hostettler; Fritz et al. US 6017577
- ❖ Momose; Akira US 4597108

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-

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2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
29 December 2008